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| EXAMINER | |
|---|---|
| COOK, CHRISTOPHER L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3737 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket@splglaw.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/823,793 | ABUHAMAD, ALFRED Z. | |
| | Examiner | Art Unit | |
| | CHRISTOPHER COOK | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Upon reconsideration by the Examiner, Claim 20 which was previously indicated as allowable, is now being rejected under 35 U.S.C. 102(e) to Poland et al.

### *Drawings*

1. The drawings are objected to because it is virtually impossible to differentiate what is being disclosed in Figs 3-11. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

2. Claims 2-7, 10, and 14-15 are objected to because of the following informalities: Claims 2-7,10 and 14-15 are objected to because they fail to further limit the computer program product and appear to be directed toward the intended use of the product. Appropriate correction is required.

### *Double Patenting*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-20 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-6 and 18-20 of copending Application No. 11089040. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the claims 1-20 involve an obvious broadening of the claims in the related application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, while Applicant discloses using formulas, none are provided. All that is shown in the tables for different planes are shifts and rotations.

7. Claims 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, for Claim 18, a spatial

mathematical relationship is not shown based on statistically generated data. Claim 20 is rejected because it is not disclosed how the formula is not "pre-set".

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular is unclear what is meant by "statistically based". Any image plan could be "statistically based" from other image data.

10. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: correlating the "acquired ultrasound image data" with the "other planes with respect to a reference plane".

## *Claim Rejections - 35 USC § 102*

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 7-8, and 14-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,699,641 to *Poland et al. "Poland".*

As for Claims 1, 7-8, and 14-17, *Poland* discloses an ultrasound diagnostic system and a computer program implemented method to acquire ultrasound image data for at least a portion of a body organ (Abstract; Column 1, Lines 22-23; Column 7, Lines 33-37) comprising a transducer (Column 3, Line 46, also, 112 in Fig 1) and a processor (137 in Fig 1). *Poland* further discloses generating and defining a reference plane for the body organ and generating and defining at least one other plane with respect to the reference plane using a spatial mathematical relationship (Column 2, Lines 28-39 and 43-45, Column 4, Lines 54-67, Column 5, Lines 28-35, Column 9, Lines 60-67-Column 10, Lines 1-13 and Lines 20-42). Furthermore, *Poland* discloses a display configured to display automatically and substantially simultaneously at least two ultrasound images corresponding to the reference plane and an other plane directly from a real time volume (Column 5, Lines 36-44; Column 6, Lines 34-35; 150 in Fig 1).

Regarding Claims 18-20, *Poland* discloses an ultrasound diagnostic system and a computer program implemented method to acquire ultrasound image data for planes of a body organ as described above. *Poland* further describes a spatial mathematical relationship based on statistically generated data (Column 9, Lines 66-67-Column 10, Lines 1-10). Further, *Poland* discloses wherein a spatial mathematical relationship comprises at least one formula that relates a reference plane to at least one other plane to define a shift or rotation

from the reference plane to at least one other plane determined by a user (Column 10, Lines 20-67).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 2-6 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,699,641 to *Poland et al. "Poland"* in view of U.S. Patent No. 6,585,647 to *Winder.*

Regarding Claims 2-6, *Poland* discloses an ultrasound diagnostic system and a computer program implemented method to acquire ultrasound image data for at least a portion of a body organ as described above. Further *Poland* is directed to a cardiology application using standard ultrasound views to visualize outflow tracts. It is a well known expedient in the art that a well known ultrasound imaging view is a four-chamber view.

*Poland* does not expressly disclose wherein the body organ is a fetal heart or fetal head, nor does Poland disclose a reference plane as a biparietal diameter of the fetal head.

*Winder* teaches a diagnostic ultrasound imaging system for imaging fetal organs and surfaces (Column 1, Lines 35-67).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program implemented method disclosed by *Poland* with a system for imaging fetal organs and structures as described by *Winder* in order to visualize and diagnose abnormalities. Further, the specific reference plan chosen would be an obvious choice depending on the specific medical procedure being performed. Therefore, when imaging the head of a fetus, a biparietal diameter reference plan would be an obvious design choice.

*15.* Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,699,641 to *Poland et al. "Poland"* in view of U.S. Patent No. 6,290,648 to *Kamiyama et al. "Kamiyama".*

As for Claims 9-11, *Poland* discloses an ultrasound diagnostic system and a computer program implemented method to acquire ultrasound image data for planes of a body organ as to provide a medical evaluation as described above.

*Poland* does not expressly disclose wherein image recognition software is used to facilitate the medical evaluation comprising steps to recognize a specific structure within an image, compare the structure with a reference image, and identify at least one of a normal and abnormal anatomical characteristic of the structure.

*Kamiyama* teaches an ultrasound diagnostic imaging apparatus (abstract) comprising image recognition software used to facilitate a medical evaluation

(Column 7, Lines 58-67-Column 8, Lines 1-30). Furthermore, *Kamiyama* teaches wherein the software recognizes a specific structure within an image, compares the structure with a reference image, and identifies at least one of a normal and abnormal anatomical characteristic of the structure (Column 8, Lines 31-67).

*Poland* and *Kamiyama* are considered analogous art because they are from the same field of endeavor with respect to diagnostic ultrasound imaging.

Therefore, it would have been obvious to a person of ordinary skill in the art, at the time the invention was made to have modified the ultrasound diagnostic system and a computer program implemented method as disclosed by *Poland* with software used in a medical evaluation as described by *Kamiyama* in order to provide a identify and type abnormalities.

16. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,699,641 to *Poland et al. "Poland"* in view of U.S. Patent No. 5,454,371 to *Fenster et al. "Fenster".*

As for Claims 12 and 13, *Poland* discloses an ultrasound diagnostic system and a computer program implemented method to acquire ultrasound image data for planes of a body organ in real time as described above.

*Poland* does not expressly disclose wherein the computer program comprises displaying each sagittal, transverse and coronal planes.

*Fenster* teaches an ultrasound diagnostic system (Abstract) wherein sagittal, transverse and coronal planes are known as conventional orienting views.

*Poland* and *Fenster* are considered analogous art because they are from the same field of endeavor with respect to acquiring multiple, diagnostic, ultrasound images.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program implemented method disclosed by Poland with an ultrasound system which acquires sagittal, transverse, and coronal planes as described by Fenster in order to acquire multiple image planes and provide a more comprehensive diagnosis.

## ***Response to Arguments***

17. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

## ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER COOK whose telephone number is (571)270-7373. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. C./
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737